International Law Office

June 7 2022

Pharmaceutical products liability litigation: impossibility pre-emption defence

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Introduction

The term "impossibility" pre-emption applies when state law is pre-empted:

> *to the extent that it actually conflicts with federal law . . . where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.*[1]

This article discusses the application of the impossibility pre-emption defence in pharmaceutical products liability cases by exploring several Supreme Court cases in the pharmaceutical context.

Wyeth v Levine

Facts

The plaintiff received an antihistamine to treat nausea via an intravenous (IV)-push (ie, an injection directly into the plaintiff's vein). The plaintiff sued Wyeth after developing gangrene, which led to amputation of the plaintiff's forearm. Though the drug's label warned of risks related to gangrene and amputation, it did not recommend that physicians administer the drug via IV drip. The plaintiff argued that had the product contained an adequate label warning about the risks of IV delivery, the injuries would not have occurred. In response, Wyeth argued that it could not have changed the label to include risks about receiving the product via an IV-push because it was previously approved by the US Food and Drug Administration (FDA), and would have needed supplemental FDA approval to change the label.

Decision

The Supreme Court disagreed and determined that, under the Food, Drug, and Cosmetic Act (FDCA),[2] a brand-name manufacturer has ultimate responsibility for a drug's label, including warnings.[3] The Court relied on the "changes being effected" (CBE) provision, which permits the manufacturer to make certain changes to a drug's label without waiting for FDA approval, including to:

- "add or strengthen a contraindication, warning, precaution, or adverse reaction"; or
- "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product".

In finding that the failure to warn claim was not pre-empted, the Court concluded that: "On the record before us, Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements."

PLIVA v Mensing

Facts

In *Mensing*, two consumers sued manufacturers of generic metoclopramide under Louisiana and Minnesota tort law claiming that the long-term use of the product caused tardive dyskinesia. The plaintiffs argued that the generic drug manufacturers were obligated to change the product's label to adequately warn consumers about the risk of developing tardive dyskinesia. In response, the generic drug manufacturers argued that federal law pre-empted the state tort laws because it was impossible for the manufacturers to comply with the federal and state requirements. Specifically, the manufacturers argued that because the FDCA requires a generic product label to be identical to the name-brand version (ie, to maintain the duty of sameness), generic drug manufacturers do not have the ability to change a drug's label.

Decision

The Court agreed with the generic manufacturers.[4] According to the Court, because it would have been unlawful under federal law for the generic manufacturers to do what state law required of them, the state law was pre-empted. The Court reasoned that "it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same".

The majority emphasised the fact that the generic manufacturers could not have undertaken to change the product label without prior "special effort" from the FDA permitting them to do so. Accordingly, because "state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action", the state law was pre-empted.

The majority also rejected an argument by the plaintiffs and the federal government as an amicus that the generic manufacturers' ability to ask the FDA for approvals to change the labels defeated pre-emption. Ultimately, the Court focused on whether the generic manufacturers could independently make changes to the product label, including through the FDCA's CBE process as a brand-name manufacturer would have been able to do. In determining that they could not, the Court held that the state law claims were pre-empted.

Mutual Pharmaceutical Company v Bartlett

Facts

In *Bartlett*, the plaintiff was prescribed brand-name Clinoril, a non-steroidal anti-inflammatory drug for shoulder pain and was dispensed a generic version of the drug. After taking the drug, the plaintiff developed acute toxic epidermal necrolysis. The drug's label did not warn of toxic epidermal necrolysis as a potential side effect and the plaintiff sued the generic manufacturer under New Hampshire state law for failure to warn and design defect claims. Following the *Mensing* decision, the plaintiff argued, and the appellate court agreed, that a generic manufacturer could choose to stop selling the product if it were unable to comply with both federal and state law.

Decision

Again, the Court disagreed with the plaintiff and appellate court, and concluded that based upon a straightforward application of pre-emption law, the state law was pre-empted because it was impossible for the generic manufacturer to comply with its federal requirements and the New Hampshire state law duties.[(5)] The Court also stated that the "stop selling" argument was "no solution" because adopting this "stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in th[e] Court's pre-emption case law."

However, the *Bartlett* decision left open one question of whether state law would be pre-empted with a theoretical design defect claim that does not involve warnings and which is parallel to the federal misbranding statute. According to the Court:

> *The misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it is 'dangerous to health' even if 'used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.'*

The Court did not reach a decision as to whether such a claim would have been pre-empted in *Bartlett* because neither party raised it at the lower court levels.

Merck Sharp & Dohme Corp v Albrecht

Facts

In *Albrecht*, the Court looked at whether state law failure to warn claims for a prescription drug for osteoporosis were pre-empted by federal law. The plaintiffs alleged that the drug's label failed to warn that it may cause "atypical femoral fractures."

Decision

The opinion contained three key rulings that have instructed courts how to determine whether a pre-emption defence is appropriate for branded pharmaceutical warning labels:[(6)]

- First, the Court held that a pre-emption defence for failure to warn is "one for a judge to decide, not a jury".
- Second, the Court enumerated what constitutes "clear evidence" for a pre-emption defence – namely:

  > *evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning.*

- Third, and finally, the Court explained that the FDA's actions can be the premise for a pre-emption defence if they are taken "pursuant to the FDA's congressionally delegated authority".

Comment

Following the Supreme Court's decisions in *Wyeth*, *Mensing*, *Bartlett* and *Albrecht*, plaintiffs' lawyers have become more inventive in their attempts to argue around impossibility pre-emption in large pharmaceutical litigations. The issues surrounding impossibility pre-emption are not going anywhere anytime soon.

As is clear from currently pending lawsuits,[(7)] there are numerous opportunities for courts to address the question of impossibility pre-emption, and how misbranding claims fit into the *Mensing* and *Bartlett* jurisprudence. Indeed, the question of *Bartlett* and plaintiffs' strategies to use it as an end-around for pre-emption will likely be addressed by the Eleventh Circuit in 2022. And, as the question continues to make its way through various district courts, it is also likely that it will percolate to other appellate courts in the not-too-distant future, until, and unless, the question is put before the Supreme Court.

Ultimately, plaintiffs in large products liability lawsuits are going to continue to argue that the allegations include parallel misbranding claims in an effort to keep all levels of the pharmaceutical supply chain in those litigations.

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Endnotes

(1) *English v Gen Elec Co*, 496 US 72, 78 (1990) (internal marks and citation omitted).

(2) 21 US Code (USC) section 301 et seq.

(3) 555 US 555 (2009).

(4) 564 US 604 (2011).

(5) 570 US 472 (2013).

(6) 139 S Ct 1668, 1672, 203 L Ed 2d 822 (2019).

(7) See, for example:

- *In Re Zantac (Ranitidine) Products Liability Litigation*, 20-md-2924 (SD Fla); and
- *In Re Metformin Marketing and Sales Practices Litigation*, 20-cv-2324 (DNJ).